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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,859	08/23/2002	Peter Fletcher-Haynes	BC-0233-US04	4599

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EXAMINER	
GUTIERREZ, ANTHONY	
ART UNIT	**PAPER NUMBER**
2857	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/064,859	FLETCHER-HAYNES ET AL.	
	Examiner	Art Unit	
	Anthony Gutierrez	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12,17-19,22-28,30-42 and 45-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-12,17-19,22-28,30-42 and 45-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 35-39, and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Stacey et al. (US Patent 5,769,811).

As to claims 35, Stacey et al. discloses a method for data entry into a blood processing machine (col. 7, lines 14-33), comprising the steps of: scanning barcode data into the blood processing machine via a barcode reader connected to the blood processing machine in data communication relationship therewith (col. 7, lines 34-54); assigning the scanned barcode data to at least one of a plurality of blood processing categories relative to a particular blood processing procedure (col. 7, lines 48-55, see also col. 5, lines 22-27, and col. 7, lines 14-47. The reference discloses that the bar-code label is an identifier for a disposable. The Examiner considers this to be scanned-barcode data. The reference discloses that a proper match is verified between the disposable and a particular protocol selected by the operator. The Examiner considers the step of verification of disposable to protocol to inherently include an initial step of assignment of disposable to protocol. The Examiner considers the particular protocol selected by the operator to be at least one of a plurality

of blood processing categories relative to a particular blood processing procedures); and using the assigned scanned barcode data in the management of at least one blood processing procedure (col. 11, lines 17-28).

As to claim 36, Stacey et al. discloses biological data relating to a source of whole blood (col. 5, lines 3-9).

As to claim 37, Stacey et al. discloses supply data relating to a supply for use in a blood processing procedure (col. 5, lines 10-12).

As to claims 38 and 39, Stacey et al. discloses storing the data in a central database (col. 2, lines 47-62).

As to claim 49, Stacey et al discloses assigning a plurality of scanned barcode data to a selected category of said plurality of categories (col. 7, lines 29 and 30, col. 11, lines 13-15, and col. 7, lines 48-55, where the reference discloses that the selected protocol (category) is associated with an identifier corresponding to allowed "types" (plural) of disposables).

As to claim 50, the sections cited in rejection of claim 35 disclose operator controlled blood processing procedures referred to as "protocols". The Examiner considers these protocols to be equivalent to "categories" as addressed previously, and considers the protocols to be equivalent, in the broadest reasonable interpretation, to operator identification and laboratory identification.

As to claim 51, Stacey et al. discloses assigning a datum of the scanned barcode data to multiple categories (col. 1, lines 47-50 and col. 7, lines 48-55 , where the reference discloses that two different protocols (SDP and PLP) use the same disposable set and the Examiner considers the datum of the scanned

barcode data to be equivalent to the disposable identifier and the two different protocols to be equivalent to multiple categories).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 4-6, 8-10, and 46-48, are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240), in view of Gilcher et al. (US Patent 6,113,554), further in view of Stacey et al. (US Patent 5,769,811).

As to claims 1, 2, 4-6, and 10, Urdahl et al. discloses a method for collecting at least one predetermined type of blood component from a source of whole blood using a blood component collection system comprising a blood component collection device and a collection procedure, said collection procedure having a plurality of control parameters associated therewith (Abstract), said method comprising the steps of: providing biological data relating to said source of whole blood (col. 2, lines 56-60); obtaining historical data from a centralized location (col. 2, lines 61-63); identifying at least one of a desired yield of said at least one predetermined blood component or a time period for duration of the collection procedure (col. 2, line 64- col. 3, line 21); performing a first deriving step comprising deriving a magnitude for at least one

of said control parameters from at least two of said providing, obtaining and identifying step (col. 8, line 65 to col. 9, line 34); using said magnitude of said at least one of said control parameters obtained during said first deriving step to control the operation of said blood component collection system (col. 9, lines 35-55); and performing said collection procedure on said blood component collection device using said at least one of said control parameters obtained during said first deriving step to control at least one of the collection of said desired yield of said at least one predetermined blood component from said source of whole blood or the time period of duration of said collection procedure, thereby providing optimizations (col. 23, lines 21-34).

Urdahl et al. discloses an information management system in a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data as addressed above and in col. 5, lines 6-40). It is in the form of a central input station such as an IBM compatible PC and attendant software (col. 5, lines 6-8).

Urdahl et al. does not specifically disclose the use of a database.

Gilcher et al., however, discloses using a database in a whole blood collection system (Title) for collecting and retrieving donor historical data, procedural, and run data (col. 9, line 35-col. 10, line 54). Gilcher et al. teaches that such a database allows for necessary correlation between a donor's information and the blood collected (col. 10, lines 24-33) and facilitates later retrieval and analysis (col. 10, lines 51-54).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to implement a database, as taught by Gilcher et al. at the

central input station of Urdahl et al. in order to bypass the use of time consuming manual entry of data and possible human error, thereby benefiting from the ability to properly correlate data and easily retrieve it.

The combination of Urdahl et al. and Gilcher et al. discloses a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database as addressed above.

Neither reference specifically teaches the use of a bar-code reader for data communication in the blood processing environment.

Stacey et al., however, teaches the use of a bar-code reader in a blood processing environment, as addressed above, and specifically teaches that it is a preferred method for data communication with respect to convenience and economy (col. 7, lines 34-65).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to use a bar-code reader for data communication, as taught by Stacey et al., in the blood processing environment as disclosed by Urdahl et al. and Gilcher et al., in order quickly and accurately process and verify data related to extracorporeal blood processing.

As to claim 8, Urdahl et al. discloses stored run data that includes blood component loss data (col. 25, lines 34 and 49).

As to claim 9, Urdahl et al. discloses stored run data that includes donation interval data (col. 25, lines 1 and 21).

As to claim 46, Stacey et al discloses assigning a plurality of scanned barcode data to a selected category of said plurality of categories (col. 7, lines

29 and 30, col. 11, lines 13-15, and col. 7, lines 48-55, where the reference discloses that the selected protocol (category) is associated with an identifier corresponding to allowed "types" (plural) of disposables).

As to claim 47, the sections cited in rejection of claim 35 disclose operator controlled blood processing procedures referred to as "protocols". The Examiner considers these protocols to be equivalent to "categories" as addressed previously, and considers the protocols to be equivalent, in the broadest reasonable interpretation, to operator identification and laboratory identification.

As to claim 48, Stacey et al. discloses assigning a datum of the scanned barcode data to multiple categories (col. 1, lines 47-50 and col. 7, lines 48-55 , where the reference discloses that two different protocols (SDP and PLP) use the same disposable set and the Examiner considers the datum of the scanned barcode data to be equivalent to the disposable identifier and the two different protocols to be equivalent to multiple categories).

5. Claims 7, 11, 12, 17-19, 22-28, 30-32, 40-42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240), in view of Gilcher et al. (US Patent 6,113,554), further in view of Stacey et al. (US Patent 5,769,811), still further in view of Langley et al. (US Patent 6,233,525 B1).

The combination of Urdahl et al., Gilcher et al., and Stacey et al., discloses a centralized location, in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database and barcode scanning procedures as addressed above. Finalization

of the procedure by generating written reports is further addressed (Urdahl et al.- col. 24, lines 34-47; Gilcher et al. –col. 10, lines 46-65).

None of the references specifically disclose the incorporation of relative need or demand data into the method.

Langley et al., however, discloses a blood component collection system in which blood components are collected from donors based on demand and/or existing inventory thereby providing inventory control (col. 2, lines 13-51), including monitoring the status of current blood processing procedures as well as discriminating between available procedures based on need for blood products from a selected blood supplier, where donor management issues are addressed (col. 21, lines 17-48).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to incorporate relative need and demand considerations as taught by Langley et al., in the method of for blood component collection as disclosed in the above combination in order to maximize collection of blood in a way that as few donations as possible go to waste.

6. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urdahl et al. (US Patent 5,658,240), in view of Gilcher et al. (US Patent 6,113,554), further in view of Stacey et al. (US Patent 5,769,811), still further in view of Poulsen et al. (US Patent 6,656,114 B1).

The combination of Urdahl et al., Gilcher et al., and Stacey et al., discloses a centralized location, in a whole blood collection system, for handling donor

historical data, procedural data, and run data, including the use of a centralized database and barcode scanning procedures as addressed above.

None of the references specifically teach the use of wireless communication subsystem or orbital satellite communications equipment.

Poulsen et al., however, teaches a system for communicating information regarding a patient's medical record from a central server that includes a wireless local are network, and a satellite link (col. 16, lines 20-59). These features allow the system to provide warnings or alarms and to facilitate time efficient communication (col. 16, lines 53-59).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to incorporate wireless and satellite communication equipment, as taught by Poulsen et al. into the centralized database of the combination of Urdahl et al. and Gilcher et al., which includes donor historical data, in order to access and submit donor data to the centralized database more rapidly, with less effort, and in order to provide the database with the most up to date data as frequently as possible.

Double Patenting

7. Claims 1, 2, 4-12, 17-19, 22-28, 30-42, and 45-48 of this application conflict with claims 1, 2, 4, 6-30, 33-35, 42-44, 84-88, and 91 of Application No. 09/797,325.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is

required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

8. Claims 1, 2, 4-12, 17-19, 22-28, 30-32, 35-42, and 45-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-30, 33-35, 42-44, 84-88, and 91, of copending Application No. 09/797,325, in view of Stacey et al. (US Patent 5,769,811). This is a provisional obviousness-type double patenting rejection.

Claims 1, 2, 4, 6-30, 33-35, 42-44, 84-88, and 91 of copending Application No. 09/797,325 are directed to a centralized location in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database and include the incorporation of relative need or demand data into the method as addressed above.

The claims do no mention the use of a bar-code reader for data communication in a blood processing environment.

Stacey et al., however, teaches the use of a bar-code reader in a blood processing environment, as addressed above, and specifically teaches that it is a preferred method for data communication with respect to convenience and economy (col. 7, lines 34-65).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to use a bar-code reader for data communication, as taught by Stacey et al., in the blood processing environment as claimed in

claims of the copending application in order quickly and accurately process and verify data related to extracorporeal blood processing.

9. Claims 33 and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/797,325, in view of Stacey et al. (US Patent 5,769,811), further in view of Poulsen et al. (US Patent 6,656,114 B1). This is a provisional obviousness-type double patenting rejection.

Claim 1 of copending Application No. 09/797,325 is directed to a centralized location in a whole blood collection system, for handling donor historical data, procedural data, and run data, including the use of a centralized database and including the incorporation of relative need or demand data into the method as addressed above.
The claims do no mention the use of a bar-code reader for data communication in a blood processing environment.

Stacey et al., however, teaches the use of a bar-code reader in a blood processing environment, as addressed above, and specifically teaches that it is a preferred method for data communication with respect to convenience and economy (col. 7, lines 34-65).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to use a bar-code reader for data communication, as taught by Stacey et al., in the blood processing environment as claimed in the claims of the copending application in order quickly and accurately process and verify data related to extracorporeal blood processing.

The claims and the patent to Stacey et al. do not mention the use of wireless or satellite communication systems or equipment.

Poulsen et al., however, teaches a system for communicating information regarding a patient's medical record from a central server that includes a wireless local are network, and a satellite link (col. 16, lines 20-59). These features allow the system to provide warnings or alarms and to facilitate time efficient communication (col. 16, lines 53-59).

It therefore would have been obvious to one of ordinary skill in the art at the time of invention to incorporate wireless and satellite communication equipment, as taught by Poulsen et al. into the centralized database of the combination of Urdahl et al. and Gilcher et al., which includes donor historical data, in order to access and submit donor data to the centralized database more rapidly, with less effort, and in order to provide the database with the most up to date data as frequently as possible.

Response to Arguments

10. Applicant's arguments filed 10/20/04 have been fully considered but they are not persuasive.

The Applicant has amended claims and added new claims to include features related to scanned barcode data as it relates to particular types of blood processing procedures and to determining a relative demand or need for particular blood products. The Examiner has adjusted his rejection, including his provisional Double Patenting rejection, to properly address the amendments and additional claims, and included new references when necessitated, but

maintains his original grounds and interpretation of all previously relied on references.

The Examiner has, in his rejection of claim 35, specifically stated his interpretation of the cited prior art (Stacey et al.; US Patent 5,769,811) to clearly distinguish why he considers the Applicant's amendment, with respect to this claim, to fail to overcome the cited section. The Examiner maintains this interpretation of the cited reference for claims dependent on claim 35 and for all combinations in which the reference is relied upon to teach this particular subject matter. The Examiner considers this interpretation to address many of the Applicant's remarks.

The Examiner considers the statement in the cited section of Stacey et al. that "the array reads this code and conveys the information to appropriate processing components (described below) in the blood-processing machine which verify a proper match..." to indicate that the scanned data is manipulated consistent with pages 75-77 of the specification, but notes his interpretation is that of the broadest reasonable interpretation and acknowledges that although examples or embodiments of manipulation are shown in the specification, they were not claimed explicitly. Nor were the words that are used in the claims defined in the specification to require these limitations. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to disputed terms. Constant v. Advanced Micro-Devices Inc., 7 USPQ 2d 1064.

The Examiner disagrees with the Applicant and believes that the reference does teach the features of all new claims and has incorporated

additional prior art as necessitated in rejection of claims amended to include limitations related to determining a relative demand or need for particular blood components.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Gutierrez whose telephone number is (571) 272-2215. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc Hoff can be reached on (571) 272-2216. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/4/05

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